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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,168	09/25/2003	Gil M. Vardi	1001.2278101	2222
28/075 7590 04/06/2010 CROMPTON, SEAGER & TUFTE, LLC 1221 NICOLLET AVENUE SUITE 800 MINNEAPOLIS, MN 55403-2420				
EXAMINER				
HOUSTON, ELIZABETH				
ART UNIT		PAPER NUMBER		
3731				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/670,168

Applicant(s)

VARDI ET AL.

Examiner

ELIZABETH HOUSTON

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3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4, 5, 8, 28-30, 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4, 5, 28-30, 32, 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Priority

1. For the record, claims 4, 7, 17 and 22 claim subject matter that does not have support in the parent case (09/860,744), therefore they will not receive the benefit of the earlier filing date.

Claim Objections

2. Claim 33 is objected to because of the following informalities: Claim 33 is dependent from a claim that has been canceled. Since the subject matter of claim 31 has been incorporated in to claim 28, claim 33 will be treated as dependent from claim 28 for the purpose of applying art. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 32 recites the limitation "the bond" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4, 5, 8, 28-30, 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keith (US 6,273,879) in view of Adams (US 6,099,497).
6. Keith discloses a catheter system comprising: a catheter including a proximal end and a distal end, the catheter comprising: a first tubular member/first catheter (for example 22 and 24; C5:L33-40), including a proximal end (for example near 28) and a distal end (34), the first tubular member defining an inflation lumen (62 and 104) of the catheter and extending distally from the proximal end of the catheter; a second tubular member/first distal tube (80) defining a main guidewire lumen (52), wherein the distal end (90) of the second tubular member is a distal end of the catheter and the proximal end of the second tubular member has a proximal end region (84) defining a proximal open end/main guidewire exit port (92), wherein the main guidewire lumen is configured to receive a main vessel guidewire therethrough (C7:L31-35), wherein the second tubular member is at least partially disposed within the inflation lumen of the first tubular member (Fig 2; C7:L12-21); a balloon (26) including a proximal waist (36) coupled to the first tubular member adjacent to the distal end of the first tubular member and a distal waist (40) coupled to the second tubular member adjacent to the distal end of the second tubular member (C8:L3-16).
7. Keith does not disclose a branch guidewire enclosure or a stent. However, Adams discloses a balloon catheter that is designed to accommodate delivering a stent to an ostium or bifurcation. Adams incorporates a two guidewire system using two separate guidewire lumens which is well known in the art (see for example 136 in

any of figs. 14a-18). In particularly a branch guidewire enclosure/second distal tube (for example 166, 172 or 182) positioned alongside the first tubular member, wherein the branch guidewire enclosure defines a lumen (136) configured to receive a branch vessel guidewire therethrough (C10:L9-17), the branch guidewire enclosure including a proximal end region (where the proximal end region is the portion that is between the proximal end of the balloon and the guidewire port described at C10:L18-23) having a proximal end (where the proximal end of the proximal region is at the guidewire port described at C10:L18-23) and a distal end region (C10:L9-17), the proximal end of the branch guidewire enclosure defining a proximal open end/branch guidewire exit port (C10:L18-23); and a stent (For example Fig.7a, 64) having a lumen and a side opening (68) in a wall thereof, the stent positioned about at least a portion of the balloon, and wherein a distal portion of the branch guidewire enclosure is positioned through the lumen of the stent (C11:L24-30) and exits at the side opening; wherein the branch guidewire enclosure is bonded to the first tubular member only at the proximal end region of the branch guidewire enclosure [For example Fig 18 and C12:L30-43. Also note that the claim requires that the guidewire enclosure is bonded to the first tubular member only at the proximal end region, which does not eliminate the guidewire enclosure being bonded to other structures, such as the balloon. Also note that the proximal end region is defined by the examiner as the part of the guidewire enclosure that is between the proximal end of the balloon and the guidewire port, and so if any or all of this portion is bonded to the tubular member it would meet the limitation of the claim], wherein the main guidewire exit port and the branch guidewire exit port are

located proximal of the stent and distal of the proximal end of the catheter (C10:L18-23). With respect to claims 32 and 33, the second distal tube is detached from the first distal tube outside of the bond and the second distal tube does not include a balloon (see Fig. 18 and C12:L30-43).

8. It would have been obvious to one having ordinary skill in the art at the time of the invention to modify the balloon of Keith in order that it is capable of delivering a stent. It is well known in the art to use catheters similarly structure to Keith for delivering stents and so it would be well within the skill of the ordinary artisan to use the balloon for stent delivery. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a branch guidewire enclosure to the balloon such that the device would be capable of delivering a stent to an ostium or bifurcation. Doing so would allow the user to precisely deliver a stent to an ostium or a bifurcation. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the guidewire structure such that it is bonded to the first tubular member of Keith since the first tubular member is the outermost surface of the catheter.

9. With respect to claims 28 and 4: Klein discloses a bonding material coupling the first tubular member and the second tubular member (C7:L22-30). It would have been obvious to one having ordinary skill in the art at the time of the invention to use a similar bonding material to couple the branch guidewire enclosure to device. Since the guidewire port would necessarily need to be bonded or coupled in some manner, it is common sense to do it in the same manner that other elements of the device are being coupled or bonded.

10. With respect to claims 5, 8 and 30, it would have been obvious to one having ordinary skill in the art at the time of the invention to modify the location of the exit ports for the guidewires and to modify the length of the guidewires depending on the use of the device. For example, the location of the ports will vary depending on the size of the catheter and size of patient it is used in as well as the location in the body where the device is being delivered. Such a modification would have involved a mere change in the size of a component, which is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Response to Arguments

11. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. H./
Examiner, Art Unit 3731

/Anh Tuan T. Nguyen/
Supervisory Patent Examiner, Art Unit 3731
4/3/10